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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,195	05/24/2001	William L. Hunter	110129.420C2	3009

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 12/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/865,195

Applicant(s)

HUNTER ET AL.

Examiner

Brian Szmaj

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-357 is/are pending in the application.
- 4a) Of the above claim(s) 10,190,195,209-219 and 355-357 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9,11-189,191-194,196-208 and 220-354 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

1. Applicant's election without traverse of Group I and the Species Election of: seeds; Method of treating in Claims 220-320; poly(lactic acid); alkylating agents; and cancer in Paper No. 9 is acknowledged.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

3. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4. Claims 1-8, 13-189, 193-208 and 220-354 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-8, 13-189, 193-213, 217-354 of copending Application No. 09/712,047. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

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5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 12 and 192 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-12 and 190-192 of copending Application No. 09/712,047. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the current application are written as the combination of the above claims in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 87, 89 and 265-273 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 265 recites the limitation "the prostate" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim.

4. Claims 87 and 89 recites the limitation "the wire" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 87 and 89 are being examined by the Examiner as though "the wire" is supposed to be "the seed".

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 5, 7-9, 11, 12, 15, 18, 19, 57-63, 84-92, 113-120, 182-185, 189, 191, 193, 199, 201, 207, 208, 220, 221, 223 and 230 are rejected under 35 U.S.C. 102(e) as being anticipated by Mavity et al.

Mavity et al discloses a method and absorbable brachytherapy and chemotherapy delivery devices, and further discloses a device that locally administers radiation and a


cell-cycle inhibitor; a radioactive seed; the radiation source is Ir-192; a cell-cycle inhibitor positioned adjacent to the radioactive source; the cell-cycle inhibitor is positioned on the outer surface of the seeds; the inhibitor is positioned on the seeds prior to the placement in the tissue, and the carrier material is selected to release the inhibitor when in contact with tissue; the inhibitor is carried by the outer member; the outer member is a coating at least partially covering the outer surface of the seed; administering the device to a patient to treat cellular proliferation; the cellular proliferation is due to cancer; the radioactive source is administered into a body cavity or directly into body tissue; the inhibitor is an alkylating agent; administering the cell-cycle inhibitor and radiation source to the region of the prostate to treat a hyperproliferative disease; the hyperproliferative disease is prostate cancer; and a cell-cycle inhibitor coated radioactive seed. See Column 4, lines 57-67; Column 6, lines 13-26; Column 7, lines 6-11; Column 11, lines 38-48; and Column 12, lines 31-33. Mavity et al discloses the use of anti-angiogenic compositions for use with the device in Column 4, line 67. It is well known to one of ordinary skill in the art that alkylating agents are a form of an anti-angiogenic composition that is used during cancer therapy.


Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited art discloses alkylating agents as being anti-angiogenic.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmalec whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.


BS
December 5, 2002


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